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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,840	12/01/2000	Johnatan Bacon	9463-014-999	4238
20583	7590	11/18/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,840

Applicant(s)

BACON ET AL.

Examiner

Gollamudi S Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The amendment, change of address and the affidavit filed on 5-18-04 are acknowledged.

Claims included in the prosecution are 1 and 3-19.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 3-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The difference between gelling agent in the independent claims and starches and others recited in claims 8 and 17 is unclear. The agents recited in the dependent claims are gelling agents. The examiner suggests naming the specific gelling agents in the independent claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 9-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazer (5,160,742).

Instant claim recites a composition wherein the coating material is a prolamin in an amount of about 30 % to 100 % of the total weight. The composition further contains 0 to 20 % gelling agent.

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Mazer discloses acetaminophen sustained release formulation, which is coated with Zein amounts of 10 to 70 % of the total weight of the core. The composition further contains excipients such as binders and fillers abstract, col. 7, lines 10-45, Examples and claims, claim 18 in particular).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal by itself or in combination with Baichwal as set forth in the previous action.

Rosenthal teaches a sustained release composition in which prolamins are present from about 20% to about 45% of the total weight of the composition (Col. 1, lines 33-46).

Rosenthal teaches excipients such as starch can be included in the composition (Col. 2, lines 35-39). Starch is a known hydrocolloid material. Although Rosenthal does not teach the amount of starch in the composition, it would have been obvious to one of ordinary skill in the art to manipulate the amounts of starch to obtain the desired release profiles.

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Baichwal teaches a sustained release composition comprising an active agent and excipients (Page 2, lines 5-24).

The excipient matrix may include one or more heteropolysaccharide, preferably xanthan gum (Page 4, lines 27-35), a cross-linking agent (Page 5, line 19 - Page 6, line 3), hydrophobic material such as zein (Page 7, lines 18-32) and an active agent. The amount of the heteropolysaccharide taught by Baichwal falls within the claimed amounts (claim 1). The hydrophobic material may be present in the composition in amounts from about 1% to about 20% by weight of the final formulation (Page 8, lines 1-10). The active agent may be an antihistamine, analgesic, anti-inflammatory agent, anti-epileptic agent, anti-emetics agent, vasodilator, anti-tussive agent, anti-asthmatic agent, anti-spasmodic, hormone, diuretic, anti-hypotensive agent, antibiotic and others (Page 12, line 17 - Page 13, line 7). The composition may further contain an inert pharmaceutical diluent such as a starch (Page 17, Claim 1).

One of ordinary skill in the art would be further motivated to use the claimed amounts of a gelling agent in the compositions of Rosenthal since Baichwal teaches that these amounts are routinely used in sustained release formulations.

Although this is a new rejection, the examiner would address applicant's arguments regarding Baichwal. Applicant argues that there is no motivation to combine Baichwal since in Baichwal the hydrophobic material is added to slow the hydration of the gums, but the amount of the hydrophobic material should be in an amount that will slow the rate of release of the medicament without disrupting the hydrophilic matrix formed upon exposure to an environmental fluid. According to applicant, this amount

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taught by Baichwal is no greater than 20 % whereas, Rosenthal teaches a sustained release composition comprising from about 20 to 45 percent. These arguments are not found to be persuasive for the following reasons. First of all, as noted from Baichwal on col. 6 referred by applicant, the amounts are preferred amounts. That means one of ordinary skill in the art could manipulate this amount to obtain the desired release rate. Secondly, as noted from instant specification on page 14, last two lines, the lower limit of prolamin is 20 % which is the upper limit taught by Baichwal. Finally, it should be pointed out that from the references cited it is clear that these two components control the release rates of the active agents and therefore, one of ordinary skill in the art would be motivated to vary the amounts to obtain the desired release rates.

Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazer cited above by itself or in combination with Rosenthal and Baichwal also cited above.

Mazer as pointed out above, discloses acetaminophen sustained release formulation. According to Mazer, the core contains the active agent excipients such as binders and fillers. The Binders according to Mazer are zeins and gums and alginates or mixtures thereof and present up to 80 % of the core (abstract, col. 7, lines 10-45).

The teachings of Rosenthal which discloses 20 to 45 % of prolamins (Zein) and those of Baichwal disclosing various gums in claimed amounts have been discussed above.

It would have been obvious to vary the individual amounts of the binders such as zein and gums within 80 % since Mazer is suggestive of these amounts to obtain the

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best possible results. One of ordinary skill in the art would be motivated further to use the claimed amounts of Zein and gums since the references of Rosenthal, and Baichwal show that these amounts are routinely practiced in the art.

Applicant's arguments based on Lorenzo Fabiano Bagarollow have been fully considered, but are not found to be persuasive since these arguments are based on his interpretation of the prior art's teachings and not supported by any experimental data.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK